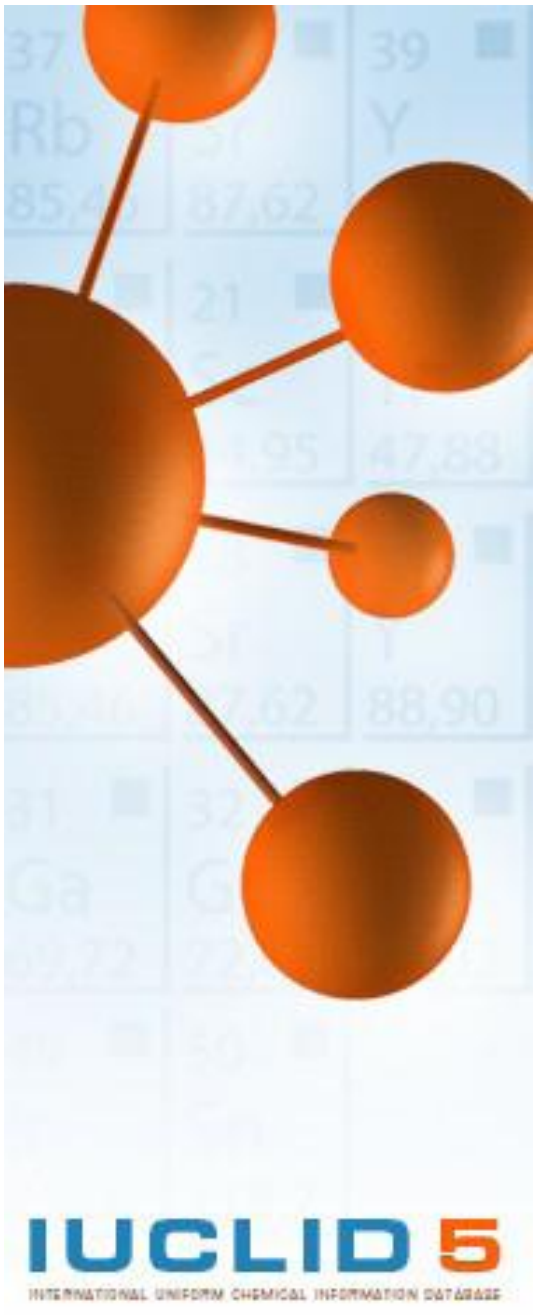


IUCLID 5
Guidance and Support

IUCLID 5
Technical Completeness Check Plug-in
User Manual

ECHA EUROPEAN CHEMICALS AGENCY | OECD

IUCLID 5 is developed by the European Chemicals Agency in association with the Organisation for Economic Co-operation and Development

February 2013 v1.6

Table of contents

1 Principle of the Technical Completeness Check (TCC) plug-in 3
1.1 Technical Completeness Check 3
1.2 Business rules check 3
1.3 Dossier Quality Assistant 4
2 Adding the plug-in to your local IUCLID 5 installation 5
2.1 Workstation / stand-alone installation 5
2.2 Distributed installation 6
3 Launching the TCC plug-in 8
3.1 Checking multiple dossiers / substance datasets 8
3.2 Checking a substance dataset or dossier you are working on 9
4 Using the TCC plug-in 10
4.1 Checking dossiers (all supported dossier templates) 10
4.2 Checking substance datasets (for registration, PPORD, inquiry) 11
4.2.1 Step 1: select dossier type 11
4.2.2 Step 2: select the tonnage bands (only for registration substance datasets) 12
4.3 Interpretation of the TCC plug-in results table 16
4.3.1 BR/TCC tab and Dossier Quality Assistant tab 16
4.3.2 TCC plug-in results toolbar 17
4.3.3 Filtering the results table 17
4.3.4 TCC plug-in results table 19
4.4 Plug-in version information 21
Annex I – Summary of contents of TCC plug-in per dossier type 23

Table of figures

Figure 1: Launching the TCC plug-in from the home view of IUCLID 8
Figure 2: Entry field 'Select document to check' 8
Figure 3: Query selection 8
Figure 4: 'Run TCC' option on a substance dataset 9
Figure 5: Radio button for dossier type 11
Figure 6: Selection of phase-in definition, fee waiving and update status 11
Figure 7: Selection of tonnage band for an individual registration 12
Figure 8: Selection of tonnage band for a joint submission lead registration 13
Figure 9: Selection of tonnage band for a joint submission member registration 14
Figure 10: Indication of whether a safety data sheet is needed - joint submission member registration 15
Figure 11: TCC plug-in results display 16
Figure 12: Yellow rows of the TCC plug-in results table 19
Figure 13: Grey/white rows of the TCC plug-in results table 19
Figure 14: Message for failed version check 21
Figure 15: Internet connection configuration 22
Figure 16: Message for plug-in up to date 22
Figure 17: Message when new plug-in is available 22
Figure 18: TCC and Business rules version information 22

1 Principle of the Technical Completeness Check (TCC) plug-in

The aim of the TCC plug-in is to assist users in the preparation of IUCLID dossiers (e.g. REACH registration dossiers, PPORD notifications) so that they can be successfully submitted to and processed by the European Chemicals Agency. The rules included in this plug-in allow the users to perform the following checks on their dossiers or substance datasets:

- The Technical Completeness Check (TCC)
- The verification of those business rules that do not rely on information from the ECHA databases (e.g. submission history)
- A set of consistency checks to improve dossier quality

1.1 Technical Completeness Check

According to the REACH Regulation, registration dossiers and PPORD notifications are subject to a completeness check (Article 20(2)). This completeness check can be divided in two parts: the Financial Completeness Check (FCC) and the Technical Completeness Check (TCC).

The aim of the Technical Completeness Check (TCC) plug-in is to enable registrants and PPORD notifiers to check within their IUCLID 5 installation (or database) the technical completeness of their dossiers (or substance datasets) prior a submission to ECHA via REACH-IT. The plug-in also checks that a dossier (or substance dataset) will be able to pass some of the business rules.

⚠ **Note:** Although the plug-in simulates the Technical Completeness Check carried out by ECHA to the largest extent possible, it will not be able to capture exhaustively all possible scenarios in which a dossier may be found incomplete (e.g. resulting from different tonnage bands of lead and member dossiers in a joint submission). The responsibility remains with the company ensure that their submission fulfils all the relevant legal requirements.

Please refer to Data Submission Manual 5 "How to complete a technical dossier for registrations and PPORD notifications" for detailed information on how to fill in the minimum requirements in IUCLID 5. The manual is available at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

1.2 Business rules check

The TCC plug-in also incorporates several of the business rules (BR) checked at ECHA. The following REACH dossier types are supported for business rules check: Registration, Downstream user report, PPORD-, Substance in article- and Inquiry notification. In addition, the business rules check is available for the dossier types CLP notification and CLP alternative name request. From version 5.4.0 onwards, the TCC plug-in also supports the business rules check for dossiers submitted by Authorities, namely Substance Evaluation dossiers, REACH Annex XV proposals (restriction and SVHC) and CLP Annex VI (CLH) proposals.

⚠ **Note:** As some of the business rules depend on information that is stored within the REACH-IT database, the plug-in cannot simulate all the business rules checked at ECHA.

For further information on the business rule check, please refer to Data Submission Manual 4: "How to Pass Business Rule Verification ("Enforce Rules")", available at: http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

1.3 Dossier Quality Assistant

From version 5.4.3 onwards, the TCC plug-in contains a new feature. This so-called Dossier Quality Assistant has been designed to assist companies in the preparation of registration and inquiry dossiers. It contains rules of the type 'warning' that highlight some of the most common inconsistencies found in registration and inquiry dossiers. While the rule set will be extended in the future, at present the Dossier Quality Assistant module focuses on the following areas in the IUCLID substance dataset and dossier:

- Sections 1.1 and 1.2, reported as Substance Identity warnings (registration and inquiry)
- Section 3.2, reported as Quality warnings (registration, standard tonnage)
- Section 3.5, reported as Quality warnings (registration, intermediate)
- Endpoint study records, Administrative Data, reported as Quality warnings (registration)

The Dossier Quality Assistant runs automatically when users launch the TCC plug-in (version 5.4.3 or above) on their substance dataset or dossier. The results are shown in a separate screen and have no impact on the outcome of the Technical Completeness Check. However, registrants are encouraged to analyse the results obtained from the Assistant and revise their dossiers as appropriate.

The warnings given by the Dossier Quality Assistant can refer to that conflicting data have been provided; that data have been entered in an unexpected manner; or they can just be reminders highlighting the need for extra caution on a particular topic. Note, that in certain situations it may be justifiable to ignore the warnings. This should be decided after consulting the warning message and the relevant guidance documents.

⚠ **Note:** The Dossier Quality Assistant does not affect the outcome of the Technical Completeness Check performed by ECHA. It is a tool which helps registrants to avoid common data inconsistency issues and thereby improve the quality of their dossiers.

⚠ **Note:** The use of the Dossier Quality Assistant is without prejudice to the expert assessment carried out by ECHA to establish the adequacy of the information required under the REACH Regulation.

For further information on the preparation of inquiry and registration dossiers, please refer to:

- Data submission manuals (2, 4, 5, 18): http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.
- Guidance documents: http://echa.europa.eu/guidance-documents/guidance-on-reach.
- Practical guides (2–4): http://echa.europa.eu/en/practical-guides

2 Adding the plug-in to your local IUCLID 5 installation

The plug-in is based on a server side and a client side ZIP file called:

- eu.echa.iuclid.**client**.plugin.tccvalidate.ui.zip
- eu.echa.iuclid.**server**.plugin.tccvalidate.zip

The installation of the plug-in depends on your IUCLID 5 installation:

- workstation / stand-alone version or
- distributed version

2.1 Workstation / stand-alone installation

If you have installed the IUCLID 5 stand-alone software in the folder

C:\ IUCLID5

You will find the sub-folders:

C:\IUCLID5\plugins\client (folder for the client side plug-ins)

C:\IUCLID5\plugins\server (folder for the server side plug-ins)

To install the plug-in you need to copy the above-mentioned client and server side zip-files into the appropriate folders (see examples below in the table).

⚠ **Note:** For the plug-in to work properly, both of the zip-files must be copied into their respective folders – it is not enough to copy only the client side zip-file.

Important:

Do not extract the ZIP files!
Depending on your computer setting the file name may be displayed without extension (.zip).

Copy the file	eu.echa.iuclid.**client**.plugin.tccvalidate.ui.zip
into the folder	<IUCLID5-folder>**\plugins\client**
Sample	C:\IUCLID5\plugins\client\eu.echa.iuclid.client.plugin.tccvalidate.ui.zip
Hint	In the folder you will already find files like: - ClientExtensionPointRootPlugin.zip - eu.echa.iuclid.plugin.helpsystemEN.zip - eu.echa.iuclid.plugin.xform.zip

Copy the file	eu.echa.iuclid.**server**.plugin.tccvalidate.zip
into the folder	<IUCLID5-folder>**\plugins\server**
Sample	C:\IUCLID5\plugins\server\eu.echa.iuclid.server.plugin.tccvalidate.zip
Hint	In the folder you will already find files like: - ServerExtensionPointRootPlugin.zip - eu.echa.iuclid.plugin.resources.zip

The plug-in will be available after **re-starting your IUCLID 5 application**.

Tip:

If the plug-in is no longer required, the files can be removed from the folders. The plug-in will disappear from the IUCLID 5 application.

2.2 Distributed installation

You will find the sub-folders on your IUCLID 5 application server:

...\i5clientPlug-ins\remotePlugins (folder for the client side plug-ins)

...\WEB-INF\classes\plugins (folder for the server side plug-ins)

To install the plug-in you need to copy the above-mentioned client and server side zip-files into the appropriate folders (see examples below in the table).

Important:

Do not extract the ZIP files!
Depending on your computer setting the file name may be displayed without extension (.zip).

Copy the file	eu.echa.iuclid.**client**.plugin.tccvalidate.ui.zip
into the folder	<IUCLID5 WebApp-folder>**\i5clientPlugins\remotePlugins**
Sample	C:\Program Files\apache-tomcat\webapps\i5server\ i5clientPlugins\remotePlugins\eu.echa.iuclid.client.plugin.tccvalidate.ui.zip
Hint	In the folder you will already find files like: - ClientExtensionPointRootPlugin.zip - eu.echa.iuclid.plugin.helpsystemEN.zip - eu.echa.iuclid.plugin.xform.zip

Copy the file	eu.echa.iuclid.**server**.plugin.tccvalidate.zip
into the folder	<IUCLID5 WebApp-folder>**\WEB-INF\classes\plugins**
Sample	C:\Program Files\apache-tomcat\webapps\i5server\ WEB-INF\classes\plugins\eu.echa.iuclid.server.plugin.tccvalidate.zip
Hint	In the folder you will already find files like: - ServerExtensionPointRootPlugin.zip - eu.echa.iuclid.plugin.resources.zip

The plug-in will be available after **re-starting your IUCLID 5 application as well as your server (e.g. TOMCAT).**

Tip:

If the plug-in is no longer required, the files can be removed from the folders. The plug-in will disappear from the IUCLID 5 application.

3 Launching the TCC plug-in

After the installation of the plug-in, the new functionality is available in IUCLID. This can be confirmed by the appearance of a new icon in the 'Plugins' section of the home view of IUCLID (Figure 1). The plug-in can be launched from a variety of locations, according to preference and way of working.

3.1 Checking multiple dossiers / substance datasets

If the purpose is to run the plug-in on a set of dossiers or substance datasets in the IUCLID application, the following approach may be adopted. Launch the plug-in from any of the three locations shown in Figure 1 (from left to right: the TCC tool icon in the 'Plugins' section of the home view; the 'Plugins' tab in the main menu; the TCC toggle button in the toolbar).

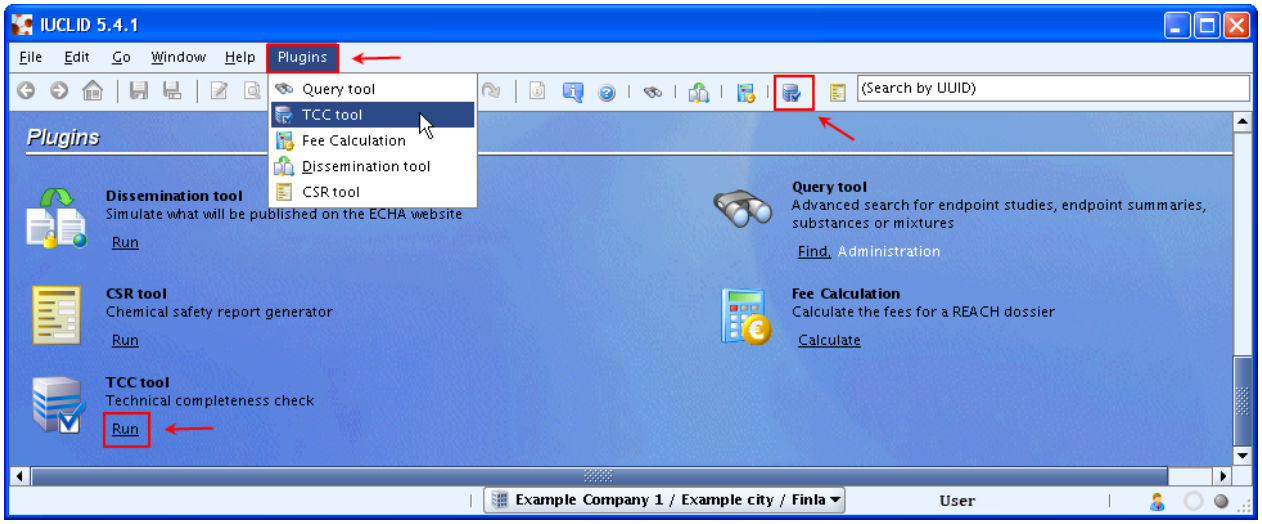


Figure 1: Launching the TCC plug-in from the home view of IUCLID

After launching the TCC plug-in, the first step in the wizard is to choose the document to be checked by clicking on the icon.

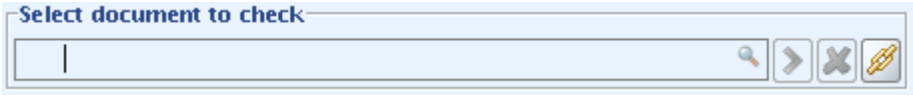


Figure 2: Entry field 'Select document to check'

This will open a query window where it will be possible to select either a dossier or a substance dataset. Note that while the rules for the document types registration, PPORD and inquiry can be checked in both dossier and substance dataset mode, the remaining supported document types can only be checked as dossiers. Please refer to Annex I of this manual for more details.

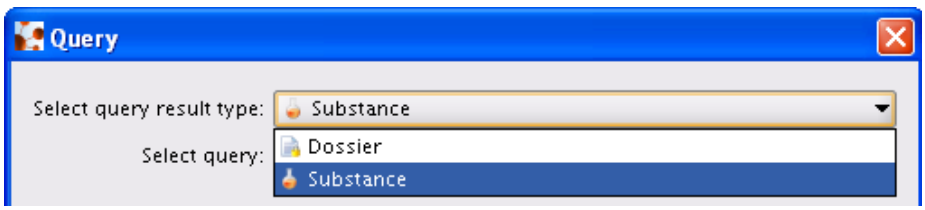


Figure 3: Query selection

Note that the TCC toggle button in the toolbar (rightmost option in Figure 1) can be used at any point to hide or display the TCC plug-in window without losing the its settings or result.

3.2 Checking a substance dataset or dossier you are working on

If you are working on a substance dataset and want to interactively check the TCC/BR/Quality rules while entering the data, the most convenient way to do this may be to, while in the 'Substance' menu, right-click the name of the relevant substance dataset in the 'Query' window and select 'Run TCC'. The plug-in window can be kept open and refreshed while entering/editing the data (see Tip in chapter 4.3.4 for instructions on refreshing).

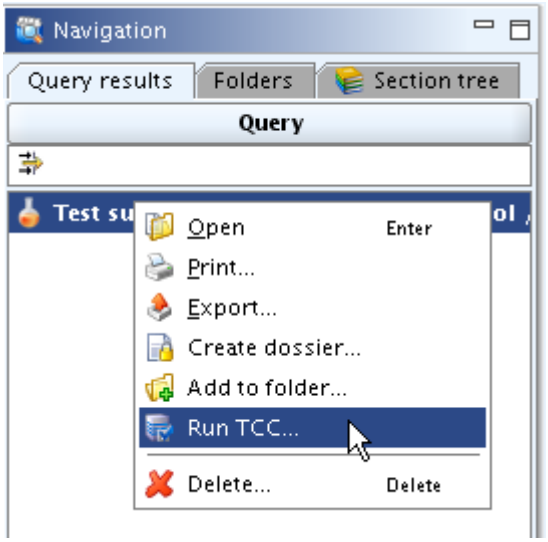


Figure 4: 'Run TCC' option on a substance dataset

Similarly, if you finished creating a new dossier and want to run the TCC plug-in on it, you can in the 'Dossier' menu right-click the name of the dossier in the 'Query' window and select 'Run TCC'. This is a convenient way to launch the plug-in on the dossier right after creating it without having to search for it. Furthermore, since the plug-in can be launched from the same location where dossier creation or dossier export takes place, the possibility of checking the incorrect dossier is reduced.

4 Using the TCC plug-in

This section explains how to use the TCC plug-in to check a dossier or a substance dataset. Depending on the dossier type, the dossier content is assessed through Business Rules checks, Technical Completeness Checks or Substance Identity and Quality checks, or their combinations. Annex I of this manual summarises which checks are available for each dossier type. Launch the TCC plug-in as described in Chapter 3.

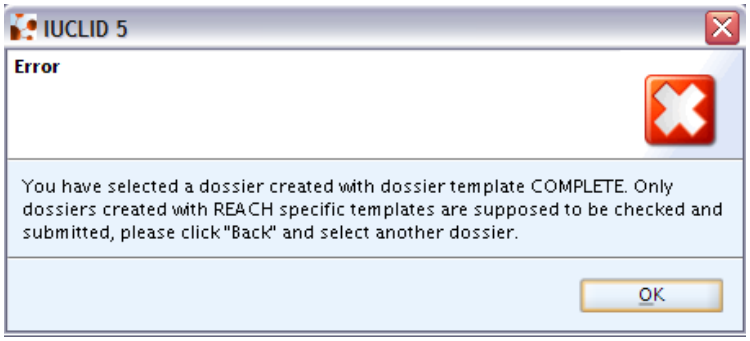
4.1 Checking dossiers (all supported dossier templates)

When the TCC plug-in is launched on a dossier, it will by default perform the check(s) corresponding to the dossier template used. These are summarised in the table in Annex I of this manual.

- For dossiers created with any of the REACH Registration templates, the plug-in performs a Technical Completeness Check according to the tonnage band information from the dossier template and header. In the same screen, the outcome of the Business Rules check is automatically reported. In addition, for these dossier templates the quality check in the Dossier Quality Assistant tab is launched.
- For dossiers created with the template REACH PPORD, the plug-in carries out a Technical Completeness Check and a Business Rules check.
- For dossiers created with the template REACH Inquiry, a Business Rules check is performed. In addition, the quality check in the Dossier Quality Assistant is launched.
- For the remaining templates supported by the plug-in (see Annex I), only a Business Rules check is performed.

Important note: For all types of dossiers, it is strongly recommended to run the TCC plug-in on the final dossier prior to submitting it in REACH-IT.

⚠ **Note:** Please keep in mind that this plug-in has been designed to validate the technical completeness of REACH registration dossiers and PPORDs. In addition, the REACH templates for Inquiry, Downstream user report and Notification of substance in article, and the CLP templates for CLP notification and CLP alternative name request, are supported for a partial business rules check. The plug-in also supports the business rules check for the following dossier types submitted by Authorities: Substance Evaluation, REACH Annex XV - Restriction, REACH Annex XV - SVHC and CLP Regulation - CLH dossier. If the validation is started on a dossier created with another dossier template the process aborts with an error similar to the one shown below:


IUCLID 5
Error
You have selected a dossier created with dossier template COMPLETE. Only dossiers created with REACH specific templates are supposed to be checked and submitted, please click "Back" and select another dossier.
OK

4.2 Checking substance datasets (for registration, PPORD, inquiry)

4.2.1 Step 1: select dossier type

Unlike dossiers, substance datasets do not correspond to a specific type of submission and therefore the user needs to select against which rules the dataset should be checked.

- If the substance has to be checked in order to create a PPORD notification dossier, select the radio button 'PPORD notification'. When clicking 'Next', you will be directed directly to step 3 where the results of the check are displayed.
- If the substance dataset will be used for the preparation of an inquiry dossier, select the radio button 'Substance identity check (for inquiry notification)'. When clicking 'Next', you will be directed directly to step 3 where the results of the check are displayed.
- Otherwise, leave the box 'Registration dossier templates' selected (selection done by default). When clicking 'Next' you will be directed to a new screen where you can select the type of registration dossier you would like to perform the Technical Completeness Check on (see Step 2 in the next chapter).

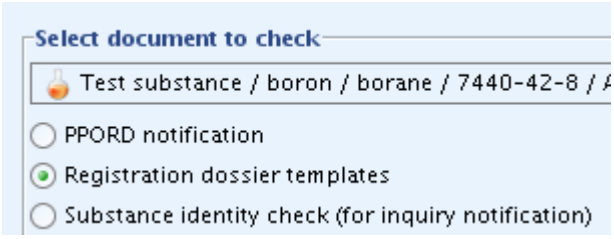

Select document to check
Test substance / boron / borane / 7440-42-8 / A
PPORD notification
Registration dossier templates
Substance identity check (for inquiry notification)

Figure 5: Radio button for dossier type

The user must also define if the dossier is for a phase-in or for a non phase-in substance. If the user wants to claim a fee waiver, this must also be indicated in Step 2 of the wizard; note that a fee waiver can only be claimed in the case stated in REACH Article 74(2). By default, the settings of the plug-in are for a phase-in substance with no fee waiving claimed. In addition, to check that the relevant 'Regulatory programme identifiers' are entered in IUCLID 5 section 1.3, the user should indicate the update status of the dossier to be submitted

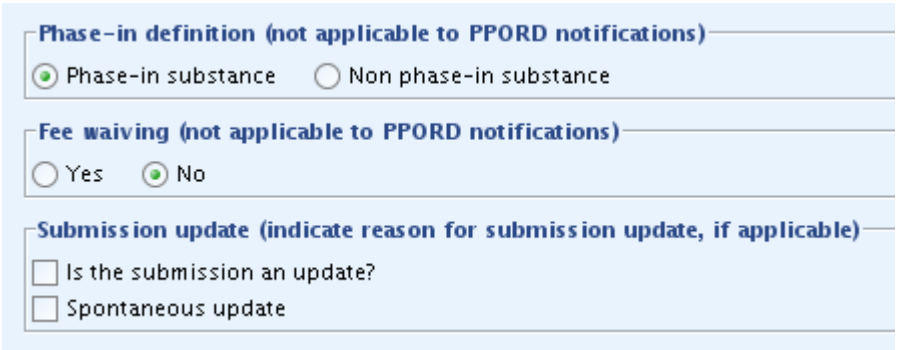

Phase-in definition (not applicable to PPORD notifications)
Phase-in substance
Non phase-in substance
Fee waiving (not applicable to PPORD notifications)
Yes
No
Submission update (indicate reason for submission update, if applicable)
Is the submission an update?
Spontaneous update

Figure 6: Selection of phase-in definition, fee waiving and update status

Important note: A IUCLID 5 dossier consists of two parts: a substance dataset, and the so-called dossier header. The dossier header is generated during the dossier creation process. It contains relevant information about the dossier, such as the tonnage band covered by the registration. The Technical Completeness Check verifies the presence of certain information in the dossier header. However, this information can only be checked for dossiers, since a substance dataset does not contain a dossier header. Therefore, even if your substance dataset is considered complete by the plug-in, it is very important that you check also the dossier you have generated from the substance dataset to verify that the dossier header is also complete.

4.2.2 Step 2: select the tonnage bands (only for registration substance datasets)

In this step the user has to define which template should be used for the Technical Completeness Check, i.e. the tonnage band of the registration dossier, if it is part of a joint submission and if it covers intermediate uses or not. After these parameters are defined, the 'Next' button becomes active.

Individual registration

If you are preparing a dossier that is not part of a joint submission, select the radio button 'No' under the heading 'Joint submission' and then use the picklists 'Registration dossier' and 'Intermediates' to indicate the relevant tonnage band. In the exceptional case of preparing a combined dossier, i.e. a registration dossier that covers both the use of a substance as an intermediate as well as non-intermediate use, select the appropriate tonnage bands from both picklists.

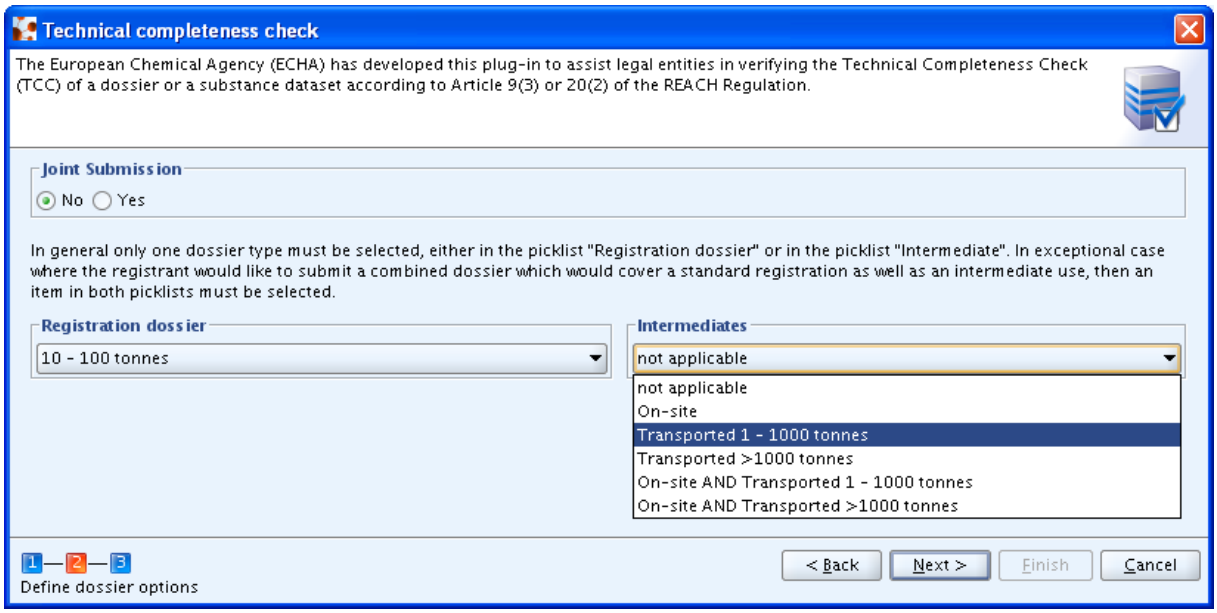

Technical completeness check
The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.
Joint Submission
No
Yes
In general only one dossier type must be selected, either in the picklist "Registration dossier" or in the picklist "Intermediate". In exceptional case where the registrant would like to submit a combined dossier which would cover a standard registration as well as an intermediate use, then an item in both picklists must be selected.
Registration dossier
10 - 100 tonnes
Intermediates
not applicable
not applicable
On-site
Transported 1 - 1000 tonnes
Transported >1000 tonnes
On-site AND Transported 1 - 1000 tonnes
On-site AND Transported >1000 tonnes
1 2 3
Define dossier options
< Back
Next >
Finish
Cancel

Figure 7: Selection of tonnage band for an individual registration

Lead of a joint submission

If you are preparing the lead dossier for a joint submission, select the radio button 'Yes' under the heading 'Joint submission'. The heading 'Role in the joint submission' will appear. Set the radio button to 'Lead registrant of a joint submission' and then select the tonnage band(s) for your dossier using the picklists 'Registration dossier' and 'Intermediates'.

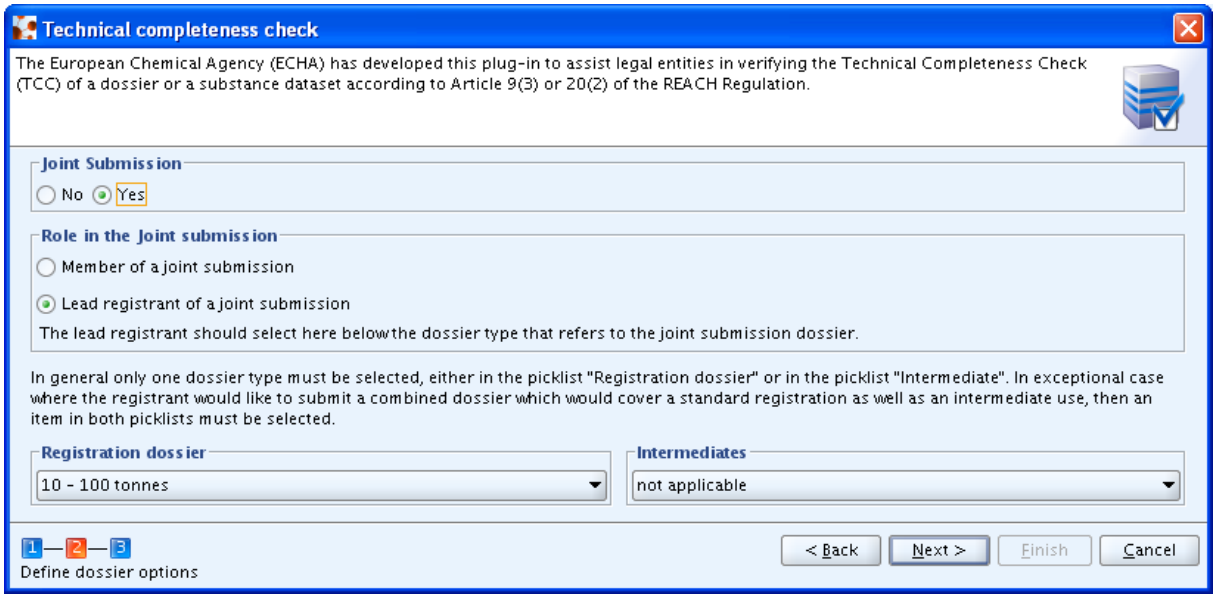

Technical completeness check
The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.
Joint Submission
No
Yes
Role in the Joint submission
Member of a joint submission
Lead registrant of a joint submission
The lead registrant should select here below the dossier type that refers to the joint submission dossier.
In general only one dossier type must be selected, either in the picklist "Registration dossier" or in the picklist "Intermediate". In exceptional case where the registrant would like to submit a combined dossier which would cover a standard registration as well as an intermediate use, then an item in both picklists must be selected.
Registration dossier
10 - 100 tonnes
Intermediates
not applicable
1—2—3
Define dossier options
< Back
Next >
Finish
Cancel

Figure 8: Selection of tonnage band for a joint submission lead registration

Member of a joint submission

Select the radio button 'Yes' under the heading 'Joint submission'. Set the radio button for the block 'Role in the joint submission' to 'Member of a joint submission' and then select the tonnage band(s) for your dossier using the picklists 'Registration dossier' and 'Intermediates'. For a correct outcome of the TCC tool, you should also indicate if the 'Chemical Safety Report' and 'Guidance on safe use' are provided by the lead registrant on your behalf or if they are included in your dossier.

Please note also that you should make a selection in the picklist 'Tonnage band of the joint submission'.

⚠ **Note:** For the endpoint sections (section 4 to 8 of IUCLID 5) a dossier for a member of a joint submission should normally contain only endpoint study records for those endpoints for which the member opts out from the joint submission. In the same manner, the member dossier should not contain any Classification and Labelling information (IUCLID 5 sections 2.1 and 2.2) unless the member indicates that they are opting out for the C&L.

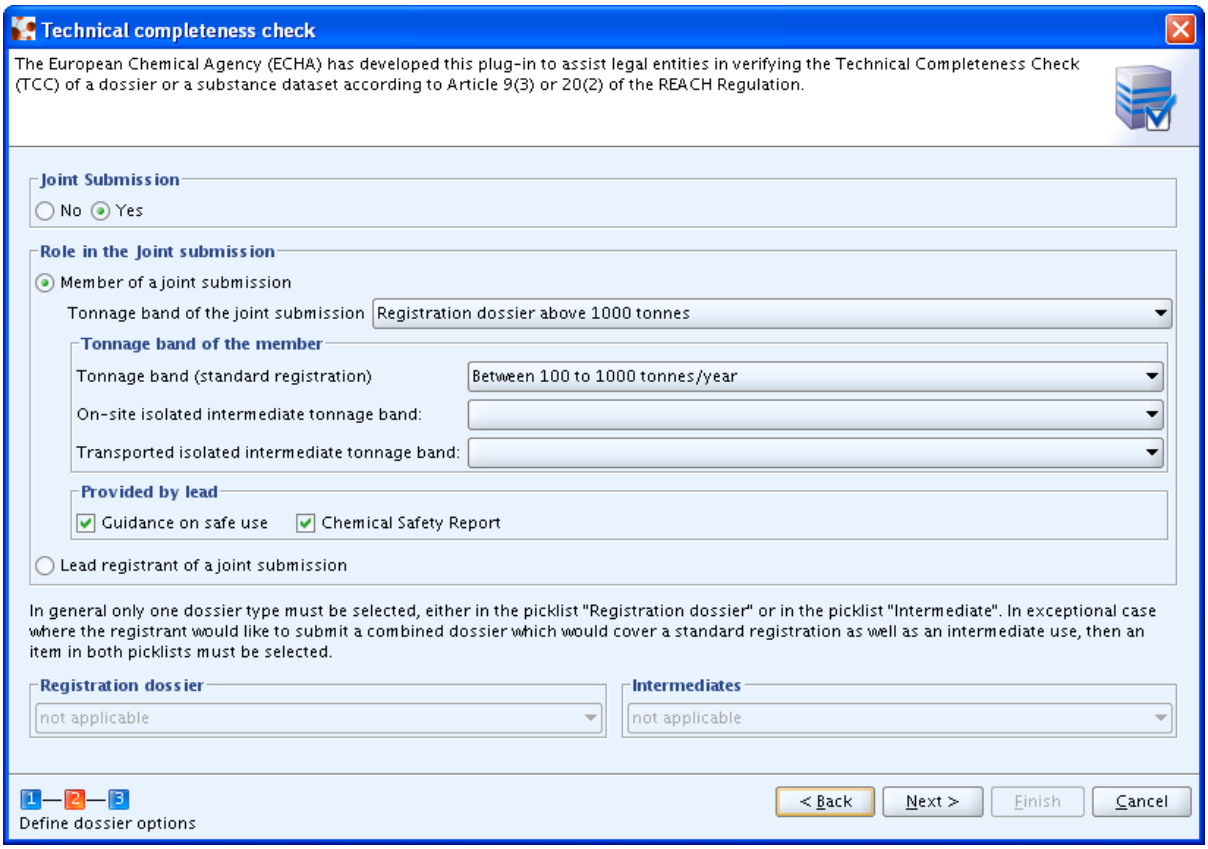

Technical completeness check
The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.
Joint Submission
No
Yes
Role in the Joint submission
Member of a joint submission
Tonnage band of the joint submission
Registration dossier above 1000 tonnes
Tonnage band of the member
Tonnage band (standard registration)
Between 100 to 1000 tonnes/year
On-site isolated intermediate tonnage band:
Transported isolated intermediate tonnage band:
Provided by lead
Guidance on safe use
Chemical Safety Report
Lead registrant of a joint submission
In general only one dossier type must be selected, either in the picklist "Registration dossier" or in the picklist "Intermediate". In exceptional case where the registrant would like to submit a combined dossier which would cover a standard registration as well as an intermediate use, then an item in both picklists must be selected.
Registration dossier
not applicable
Intermediates
not applicable
1—2—3
Define dossier options
< Back
Next >
Finish
Cancel

Figure 9: Selection of tonnage band for a joint submission member registration

⚠ **Note:** IUCLID 5.4 offers the possibility to claim confidential the information contained in the Safety Data Sheet (SDS), such as the registration number, the legal entity, and the outcome of the PBT assessment. These confidentiality claims will be charged and invoiced for all substances that require a SDS. As before, a business rule will check that all chargeable claims are supported by a justification. To determine whether the substance being registered requires a SDS or not, for joint submission member registrations that lack information on classification and/or PBT assessment, some input by the user may be needed. This information is indicated with the radio buttons that appear under the new heading 'Is a safety data sheet required for this substance?' in Step 2 of the TCC plug-in wizard (Figure 10).

The input is only asked when the substance dataset or dossier contains confidentiality claims on the safety data sheet information and the member dossier does not contain enough information to determine whether a SDS is required for the substance to be registered.

More information on the dissemination and confidentiality claims of SDS information can be found in the FAQ document "Questions and answers on dissemination and confidentiality claims of Safety Data Sheet information in IUCLID 5.4" available at: http://echa.europa.eu/support/faqs

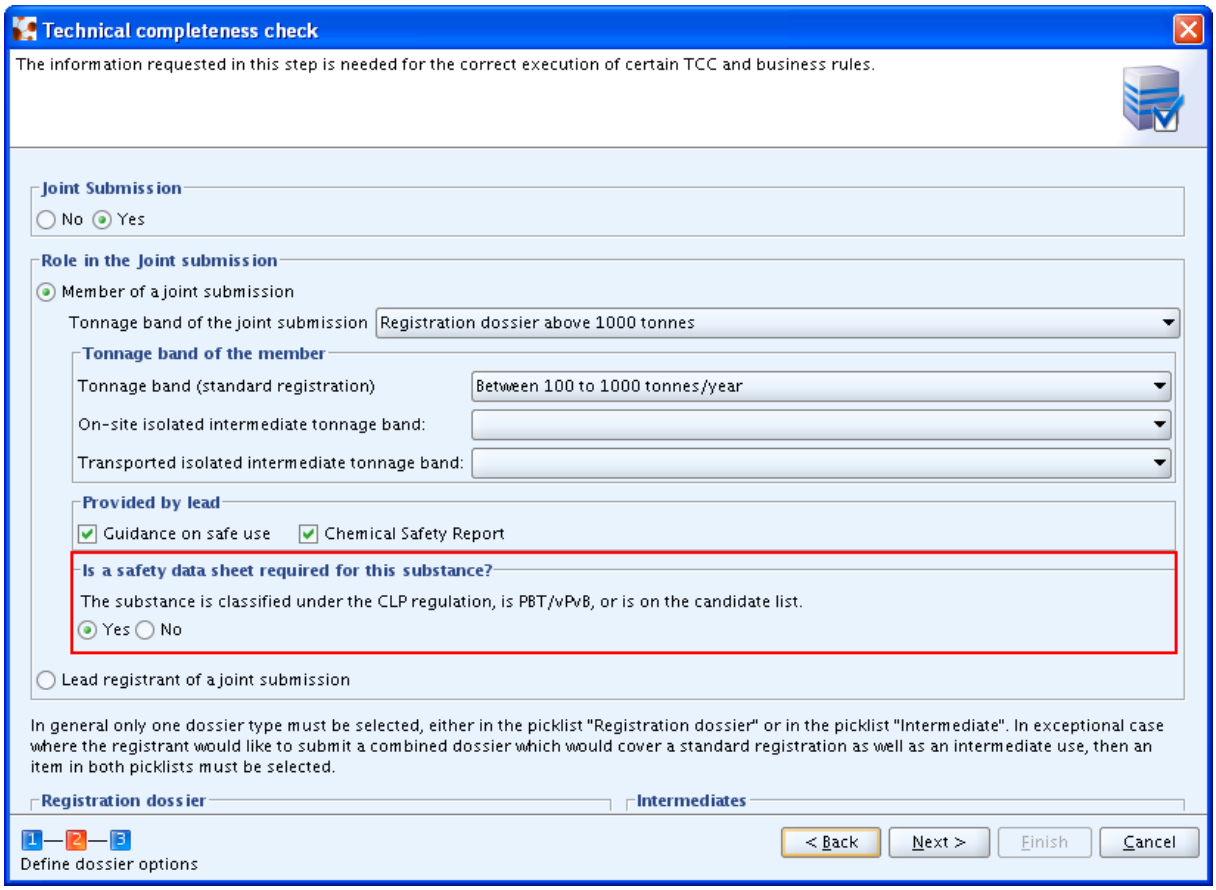

Technical completeness check
The information requested in this step is needed for the correct execution of certain TCC and business rules.
Joint Submission
No
Yes
Role in the Joint submission
Member of a joint submission
Tonnage band of the joint submission
Registration dossier above 1000 tonnes
Tonnage band of the member
Tonnage band (standard registration)
Between 100 to 1000 tonnes/year
On-site isolated intermediate tonnage band:
Transported isolated intermediate tonnage band:
Provided by lead
Guidance on safe use
Chemical Safety Report
Is a safety data sheet required for this substance?
The substance is classified under the CLP regulation, is PBT/vPvB, or is on the candidate list.
Yes
No
Lead registrant of a joint submission
In general only one dossier type must be selected, either in the picklist "Registration dossier" or in the picklist "Intermediate". In exceptional case where the registrant would like to submit a combined dossier which would cover a standard registration as well as an intermediate use, then an item in both picklists must be selected.
Registration dossier
Intermediates
1—2—3
Define dossier options
< Back
Next >
Finish
Cancel

Figure 10: Indication of whether a safety data sheet is needed - joint submission member registration

After having completed Step 2 of the TCC plug-in wizard the 'Next' button becomes active. Clicking on the 'Next' button will run the TCC rules according to the selected parameters and display the results in Step 3.

4.3 Interpretation of the TCC plug-in results table

In step 3 of the TCC plug-in wizard, the outcome of the performed check(s) is displayed (Figure 11). The different parts of the results display are further described in the following subsections. While the screenshots used in this chapter illustrate the case of a dossier type checked with Technical Completeness Check rules, Business Rules and Dossier Quality Assistant rules the interpretation of the results as described below is also valid for dossier types which are only checked by some of the modules.

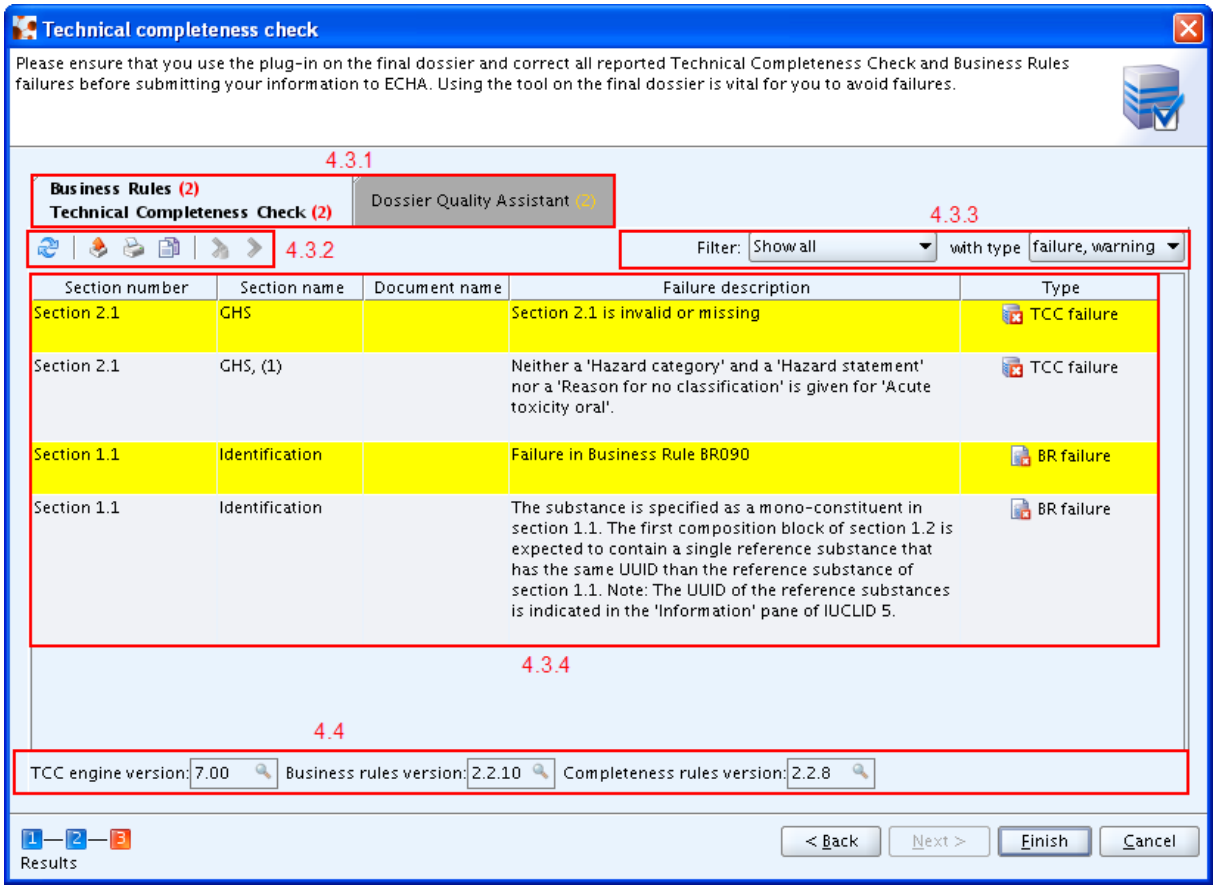

Technical completeness check
Please ensure that you use the plug-in on the final dossier and correct all reported Technical Completeness Check and Business Rules failures before submitting your information to ECHA. Using the tool on the final dossier is vital for you to avoid failures.
4.3.1
Business Rules (2)
Technical Completeness Check (2)
Dossier Quality Assistant (2)
4.3.2
4.3.3
Filter: Show all
with type failure, warning
Section number
Section name
Document name
Failure description
Type
Section 2.1
GHS
Section 2.1 is invalid or missing
TCC failure
Section 2.1
GHS, (1)
Neither a 'Hazard category' and a 'Hazard statement' nor a 'Reason for no classification' is given for 'Acute toxicity oral'.
TCC failure
Section 1.1
Identification
Failure in Business Rule BR090
BR failure
Section 1.1
Identification
The substance is specified as a mono-constituent in section 1.1. The first composition block of section 1.2 is expected to contain a single reference substance that has the same UUID than the reference substance of section 1.1. Note: The UUID of the reference substances is indicated in the 'Information' pane of IUCLID 5.
BR failure
4.3.4
4.4
TCC engine version: 7.00
Business rules version: 2.2.10
Completeness rules version: 2.2.8
Results
< Back
Next >
Finish
Cancel

Figure 11: TCC plug-in results display (the numbering corresponds with the following subsections)

4.3.1 BR/TCC tab and Dossier Quality Assistant tab

From the TCC plug-in version 5.4.3 onwards, the results window is split into two separate parts (tabs). When entering the results window, the tab that is opened by default is the one containing the results of the Business Rules and Technical Completeness Check.

By clicking on the second tab header, the Dossier Quality Assistant results can be displayed.

In the tab headers, numbers are displayed in brackets. They indicate the number of messages displayed for each rule type, with red pointing to a message of the type 'failure' and yellow pointing to a message of the type 'warning'.

4.3.2 TCC plug-in results toolbar

	Refresh the plug-in result (only for substance datasets)
	Export the result list as xml. All the plug-in results are exported in a XML file.
	Print the plug-in result
	Copy the plug-in results (can be pasted to Excel, Word…)
	Navigate to the document in the dossier (only for dossiers). If you select any row and press this button, it will open the corresponding section in the dossier which was checked.
	Navigate to the document in the substance dataset. If you select any row in the results table and press this button, it will open the substance which was checked (if the results are from a substance dataset) or the substance dataset that was used to create your dossier (if the results are from a dossier) at the corresponding section. This option is not available if you were checking a dossier but the substance dataset that was used to generate that dossier is not in your IUCLID 5 database.

Tip: A double click on any row of the plug-in results table has the same effect as clicking on the navigation buttons and . As a consequence a double click on a specific row will directly open the substance/dossier at the corresponding section.

4.3.3 Filtering the results table

Show all		All result items are displayed without filtering.
Business Rules / Technical Completeness Check tab	**Only TCC rules**	Only results with the level 'TCC failure' ( ) and 'TCC warning' ( ) are displayed in the results table.
	Only Business rules	Only results with the level 'BR failure' ( ) and 'BR warning' ( ) are displayed in the results table.
Dossier Quality Assistant tab	**Only Dossier Quality rules**	Only results with the level 'Dossier Quality warning' ( ) are displayed in the results table.
	Only Substance Identity rules	Only results with the 'Substance Identity warning' ( ) are displayed in the results table.
failure, warning		Both failures and warnings are displayed in the results table.
failure		Only the failures are displayed in the results table, not the warnings.

When the TCC plug-in is run on a dossier or substance dataset, there are six types of messages that can be displayed, depending on the dossier template selected: TCC warnings and TCC failures; BR warnings and BR failures; Dossier Quality warnings and Substance Identity warnings. TCC messages appear only for registration and PPORD dossiers or substance datasets. BR messages appear for all dossier types supported by the plug-in, as well as for substance datasets of the type registration, PPORD notification or inquiry. Substance Identity warnings appear for registration and inquiry dossiers and substance datasets. Dossier Quality warnings appear for registration dossiers and substance datasets.

TCC failure

TCC failure messages correspond to the Technical Completeness Check carried out at ECHA. If you submit your dossier without correcting the issues mentioned in the TCC failure messages, your dossier will fail the TCC in REACH-IT. These messages are flagged with the icon.

TCC warning

A TCC warning is not an indication of that your dossier will fail the Technical Completeness Check, but it suggests that some information that should normally be in your registration dossier is lacking. Therefore, you are advised to correct the issue that raised the warning message, since it could have implications for the compliance of your dossier.

BR failure

A BR failure in the plug-in is associated with a Business Rules step failure at ECHA. If you submit a dossier without correcting the issue mentioned in the message, your dossier will fail the business rules check during the submission process.

BR warning

A BR warning does not directly translate into a Business Rules step failure at ECHA, but it indicates that some information that should normally be in your dossier is missing. Therefore, you are advised to correct the issue that raised the warning message, since it could have implications for the compliance of your dossier.

Dossier Quality warnings

Dossier Quality warnings are only displayed for registration dossiers and substance datasets. A Dossier Quality warning contains important recommendations on how to improve the consistency of the selected information. The warnings can refer to the fact that conflicting data have been provided; that data have been entered in an unexpected manner; or they can simply be reminders highlighting the need for extra caution on specific topics.

You are recommended to consider all Dossier Quality warnings and address the reported inconsistencies before submitting your dossier to ECHA. Note that in certain situations it may be justifiable to ignore the warnings. This should be decided after consulting the warning message and the relevant guidance documents.

Substance Identity warnings

Substance Identity warnings are only displayed for registration and inquiry dossiers and substance datasets. A Substance Identity warning contains important recommendations on how to improve the consistency of the reported substance identity information. The warnings can refer to the fact that conflicting data have been provided; that data have been entered in an unexpected manner; or they can simply be reminders highlighting the need for extra caution on specific topics.

You are recommended to consider all Substance Identity warnings and address the reported inconsistencies before submitting your dossier to ECHA. Note that in certain situations it may be justifiable to ignore the warnings. This should be decided after consulting the warning message and the relevant guidance documents.

4.3.4 TCC plug-in results table

The rows highlighted in yellow in the TCC plug-in results table indicate the sections of the dossier/substance that gave rise to the failure/warning, or in the case of BR/Dossier Quality/Substance Identity rules, the section and the number of the rule.

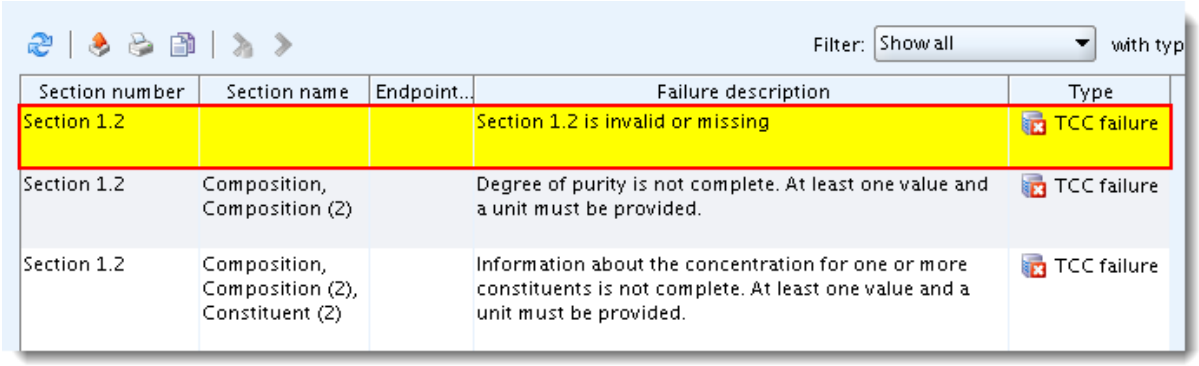

Filter: Show all
with typ
Section number
Section name
Endpoint...
Failure description
Type
Section 1.2
Section 1.2 is invalid or missing
TCC failure
Section 1.2
Composition, Composition (2)
Degree of purity is not complete. At least one value and a unit must be provided.
TCC failure
Section 1.2
Composition, Composition (2), Constituent (2)
Information about the concentration for one or more constituents is not complete. At least one value and a unit must be provided.
TCC failure

Figure 12: Yellow rows of the TCC plug-in results table

The rows in grey or white describe in more detail the fields of the dossier/substance that need to be filled, or modified, in to correct the failure/warning.

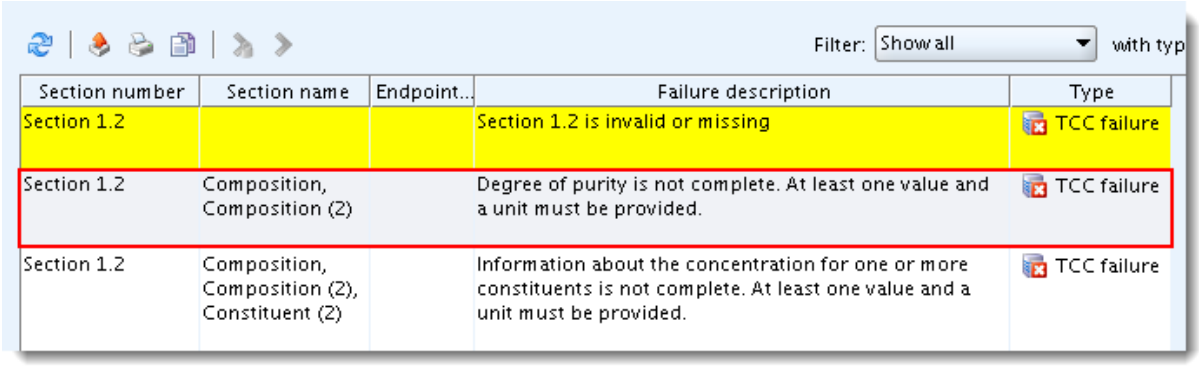

Filter: Show all
with typ
Section number
Section name
Endpoint...
Failure description
Type
Section 1.2
Section 1.2 is invalid or missing
TCC failure
Section 1.2
Composition, Composition (2)
Degree of purity is not complete. At least one value and a unit must be provided.
TCC failure
Section 1.2
Composition, Composition (2), Constituent (2)
Information about the concentration for one or more constituents is not complete. At least one value and a unit must be provided.
TCC failure

Figure 13: Grey/white rows of the TCC plug-in results table

A right mouse click on the results table opens the following menu:

Print table	The whole TCC result table will be printed.
Copy table	The whole TCC result table will be copied in the windows clipboard and can be pasted in Excel or Word, for instance.
Go to referenced document (dossier data)	This option will open the dossier that was checked with the plug-in.
Go to referenced document (raw data)	This option will open the substance dataset that was checked with the plug-in (if available in your IUCLID 5 database).

Tip: At step 3 of the TCC plug-in (results table), if you are running the plug-in on a substance dataset, it is possible to interactively correct/modify the dataset while keeping the TCC results table open. After obtaining the TCC results table in step 3:

- Click on the toggle button to hide the TCC plug-in window, or move the plug-in window aside by dragging with the mouse

- Correct the indicated failure in the substance dataset

- Click on the save button in the IUCLID 5 toolbar

- Click on the toggle button to show the TCC plug-in window if you had hidden it

- Click on the refresh button of the TCC plug-in window to see if the failure description is still present.

Specific cases where a failure indicated by the TCC plug-in may be disregarded:

There are certain cases where a TCC failure is listed in the TCC result table even if the dossier may be technically complete. These TCC failures do not mean that the dossier will necessarily fail the Technical Completeness Check but that a manual intervention will be needed from ECHA side in order to verify completeness. This is the case, for instance, with the following TCC failure:

- **Dossier header**: You are a member of a joint submission and your dossier contains an opt-out. If your tonnage band is higher than the tonnage band of the joint submission, ECHA will check that your additional information requirements have been fulfilled. If your tonnage band is not higher than the tonnage band of the joint submission then this message can be disregarded.

When the plug-in does not detect any failures/warnings for one or several of the modules in the dossier or the substance dataset, this is reported by the following disclaimer messages:

- **TCC (registration, PPORD):** Your dossier/substance dataset is considered as complete for the indicated tonnage band. However, please note that the completeness check performed by ECHA might include additional checks as for instance the relationship with other dossiers (e.g. lead versus member). These additional checks could potentially lead to different conclusions from those indicated by this tool. The use of the TCC tool is without prejudice to the obligation to submit a dossier that fulfils all relevant legal requirements.
- **BR:** No BR failures were detected by the plug-in. Please note that some of the business rules can only be checked at dossier level. Also note that due to technical reasons, the BR check performed by the plug-in does not cover all business rules checked at ECHA.
- **Dossier Quality (registration):** No quality concerns were detected by the plug-in. Please note that this tool does not carry out a full assessment of the adequacy of the information provided. The use of this tool is without prejudice to the expert assessment carried out by ECHA to establish the adequacy of the information required under article 10, 17 or 18 of the REACH Regulation.

⚠ **Note:** When updating a registration that was previously a notification under Directive 67/548/EEC for another reason than a tonnage band update, less information is required than for a standard dossier. The minimum information to be provided in this case is described in Annex 4 of Data Submission Manual 5 'How to complete a technical dossier for registrations and PPORD notifications'.

The TCC plug-in does not offer the possibility to verify the completeness of only these reduced information requirements, but will check the full requirements for the selected tonnage band. As a consequence, the TCC plug-in can be used to check the completeness of these dossiers but only the TCC failures/warnings related to the information requirements indicated in Annex 4 of Data Submission Manual 5 could be a reason for considering the dossier as incomplete. The manual is available at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

Similarly, for this type of dossier, any warnings issued by the Dossier Quality Assistant concerning sections outside the information requirements indicated in Annex 4 of Data Submission Manual 5 may be disregarded.

⚠ **Note:** As stated in section 1, the check performed by the TCC plug-in does not cover all of the verifications carried out on a dossier submitted to ECHA. It is the responsibility of the submitter to ensure that the dossier fulfils the appropriate data requirements and to monitor the outcome of the submission process in REACH-IT.

4.4 Plug-in version information

When launching the TCC plug-in, in step 1 there is a plug-in version checker at the bottom of the plug-in window. The version checker verifies the version of the currently installed TCC plug-in and displays a warning message if a newer version is available on the IUCLID 5 website. To get the version checker working an internet access needs to be established. In case a proxy server is necessary for the internet access this can be defined by pressing the plug-in checker button:

Figure 14: Message for failed version check

Afterwards, a configuration popup window will appear where you will be able to define, if necessary, a proxy hostname and a port. The vendor URL is the URL from the IUCLID 5 website which is used for the online check. The definitions are stored for each user on the server. To reset the default value for the vendor URL just press 'Reset to default URL' below the vendor URL input field.

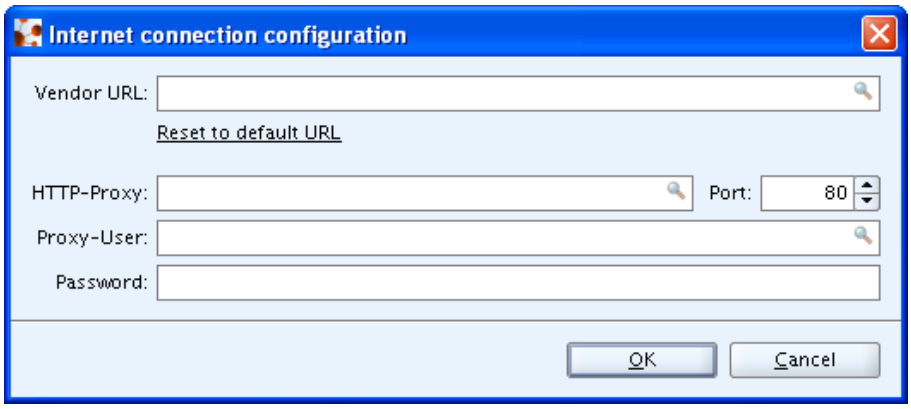


Figure 15: Internet connection configuration

If the plug-in is up to date the following status is displayed:

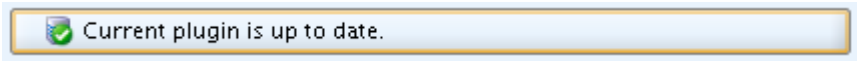


Figure 16: Message for plug-in up to date

If a newer TCC plug-in is available for update the following status is displayed:

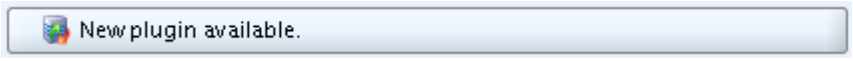


Figure 17: Message when new plug-in is available

In this latter case the new TCC plug-in should be downloaded from the IUCLID 5 website (the previous one needs to be removed and the new one installed).

In step 3 of the TCC plug-in wizard, below the Business Rules and Technical Completeness Check results table, the version information for the TCC engine, the Business rules, and the Completeness check rules are displayed (see Figure 18). Similarly, when accessing the Dossier Quality Assistant tab, the version information for the Dossier Quality rules and the Substance Identity rules are shown. In order to verify that you are using the latest version of the TCC plug-in, you may compare these version numbers with the ones listed on the download page of the TCC plug-in on the IUCLID 5 homepage.

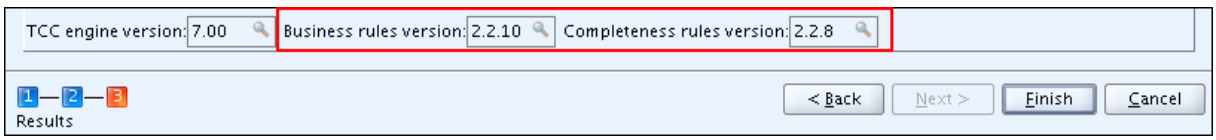


Figure 18: TCC and Business rules version information

⚠ Note: If you are uncertain about how to enter the required information in the correct format in your IUCLID 5 dossier or how to run the TCC plug-in, please contact the ECHA Helpdesk at http://echa.europa.eu/web/guest/contact. ECHA will then provide you with specific advice on how to proceed.

Annex I – Summary of contents of TCC plug-in per dossier type

		Available modules			
Regulation	**Dossier type**	**TCC**	**BR**	**Dossier Quality Assistant**	**Applicable to substance datasets**
REACH	Registration	**X**	**X**	**X**	**X**
	PPORD	**X**	**X**	–	**X**
	Inquiry	–	**X**	**X**	**X**
	Downstream user report	–	**X**	–	–
	Substance in article notification	–	**X**	–	–
CLP	CLP notification	–	**X**	–	–
	CLP alternative name request	–	**X**	–	–
REACH (auth)	*Substance evaluation*	–	**X**	–	–
	Annex XV – restriction	–	**X**	–	–
	Annex XV – SVHC	–	**X**	–	–
CLP (auth)	*Annex VI – CLH proposal*	–	**X**	–	–

European Chemicals Agency

IUCLID 5 Support

Technical Completeness Check plug-in Manual
February 2013 v 1.6

http://iuclid.eu